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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/316,163	05/21/99	SCHWAEBLE	W 3523-P-002

EXAMINER	
DIBRINO,M	
ART UNIT	**PAPER NUMBER**
1644	14

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DATE MAILED: 01/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/163,136	Schwaeble et al.
Examiner	**Group Art Unit**
Marianne DiBrino	1644

☒ Responsive to communication(s) filed on *Oct 23, 2000*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *2, 5-8, and 11-25* is/are pending in the applicat

Of the above, claim(s) *5-8 and 11-16* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *2 and 17-25* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's amendment filed 10/23/00 (Paper No. 12) is acknowledged and has been entered.

Claims 2, 5-8 and 11-25 are pending. Claims 2 and 17-25 are currently being examined.

The following rejections remain.

2. Claim 2 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The instant claims encompass a multitude molecule comprising amino acid sequences that may have any number of deletions, substitutions or additions with a low degree of homology to modules 1-4 of complement factor H. There is insufficient disclosure in the specification on such a partially modified molecule or an allelic mutant.

The specification discloses (on page 3 beginning at line 13) that partial modification of the claimed molecule is a partially modified form of the molecule which retains substantially the properties of the molecule from which it is derived, although it may have additional functionality . The specification does not disclose what substantially the properties are. The specification further discloses that partially modified molecules may be homologues with at least 40% homology with the molecules from which they are derived. The specification does not disclose the definition of an allelic mutant. Thus, at the time the application was filed, the claimed polynucleotide was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention.

3. Claim 2 stands rejected under under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 2 stands rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a molecule which consists of complement control protein modules 1-4 of human or rat complement factor H, is not enabling for a molecule comprising at least complement control protein modules 1-4 of complement factor H, nor comprising a molecule resulting from partial modification thereof, or an allelic mutant, thereof. The specification is not enabling for said molecule from a species other than rat or human consisting of at least

complement control protein modules 1-4 of complement factor H, nor consisting of a molecule resulting from partial modification thereof, or an allelic mutant, thereof. The claimed molecule encompasses molecules which are not disclosed in the specification. The specification does not enable any person skilled in the art two which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The instant claims encompass a multitude molecule comprising amino acid sequences that may have any number of deletions, substitutions or additions with a low degree of homology to modules 1-4 of complement factor H. There is insufficient disclosure in the specification on such a partially modified molecule or an allelic mutant.

The specification discloses (on page 3 beginning at line 13) that partial modification of the claimed molecule is a partially modified form of the molecule which retains substantially the properties of the molecule from which it is derived, although it may have additional functionality . The specification does not disclose what "substantially the properties" are. The specification further discloses that partially modified molecules may be homologues with at least 40% homology with the molecules from which they are derived. The specification does not disclose the definition of an allelic mutant.

There is no guidance in the specification as to what alterations result in a functional molecule. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain functional activity, and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e., its activity) are not well understood and are therefore not predictable (Ngo et al. The Protein Folding Problem and Tertiary Structure Prediction, Merz & LeGrand, Birkhauser Boston, pages 491-495, 1994, entire article, especially Section 6, paragraph 1), it would require undue experimentation for one of skill in the art to arrive at other amino acid sequences that would have functional activity. In other words, since it would require undue experimentation to identify amino acid sequences that have functional activity and because functional activity is defined as "substantially the properties" of the molecule from which it is derived", it would require undue experimentation to make the corresponding sequences. The enablement provided by the specification is not commensurate with the scope of the claims.

The following are new grounds of rejection necessitated by the amendment filed 10/23/00.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 22-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection.

The amendatory material that is not supported by the specification and claims as originally filed is as follows: the phrase "A complement system inhibiting molecule" recited in line 1 of instant claim 22.

6. Claims 2, 17, 22, 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 USPQ2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed molecule comprising complement control protein modules 1-4, 1-5 or 1-6 of complement factor H.

The instant claims encompass a molecule which comprises other than complement control protein modules 1-4, 1-5 or 1-6 of complement factor H that is from human or rat. There is insufficient disclosure in the specification on such a method using said composition.

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("

The specification discloses molecules comprising modules 1-4, 1-5 or 1-6 of human factor H (specification at page 15, paragraphs 2-4), that human factor H has been cloned previously, and that rat factor H has been cloned (specification at page 4, paragraph 6 and page 6 at paragraph 2). The specification discloses that the functionally relevant domains of rat factor H have not been mapped precisely (specification at page 15, paragraph 6). The specification discloses (on page 2, last paragraph) that in human serum, two different factor H glycoproteins of 155 kDa (FHp155) and of 43 kDa (FHp43) are known. The specification further discloses rat FH 4.3 and rat FH 1.0 (on page 6 at the second full paragraph). The specification does not disclose factor H glycoproteins from species other than human or rat.

The instant disclosure of two species, i.e., human factor H and rat factor H, does not adequately describe the scope of the claimed genus, which encompasses factor H from any species. A description of a genus may be acheived by means of a recitation of a representative number of species, defined by sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lily & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).* The specification fails to provide sufficient relevant identifying characteristics such as definitive structural features of the claimed genus. There is no information regarding the relation of structure to function. Structural features that could distinguish molecules in the genus from others excluded are missing from the disclosure.

One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function does not suffice to define the genus because it is only an indication of what the property the molecule has, and if one extends the analysis in the instant case, what the molecule does, rather than what it is. See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06. It is only a definition of a useful result rather than a definition of what achieves that result. Many such species may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin [e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Since the disclosure fails to provide sufficient relevant identifying characteristics that identify members of the genus, and given the broad genus claimed, the disclosure of rat and human complement control protein is insufficient to describe the claimed genus.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 2 and 17-25 are rejected under 35 U.S.C. 102(b) as being anticipated by pir62 Accession No. S03013. (The reference was provided in the last Office Action).

Pir62 Accession No. S03013 teaches a molecule *comprising* complement control protein modules 1-4 of human complement factor H *having* the sequence of SEQ ID NO: 9 of the instant application. Note that the claimed recitation of intended use in inhibiting complement activation in instant claims 20 and 24 does not carry any patentable weight per se. A compound is the same compound irrespective of its intended use.

With regard to instant claims 21 and 25, the property of having an enhanced efficacy when compared to Fhp155 is considered an inherent property of the reference compound. The claimed molecule appears to be the same as the art absent a showing of any differences. Since the Patent Office does not have the facilities for examining and comparing the molecule of the instant invention to those of the prior art, the burden is on applicant to show an unobvious distinction between the molecule of the instant invention and that of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

The reference teachings anticipate the claimed invention.

Applicant's arguments filed 10/23/00 have been fully considered but they are not persuasive.

With regard to Applicant's comments in said amendment on page 4 directed to unexpected results, i.e., that Applicant has found and demonstrated that modules 1-4, 1-5 and 1-6 of the protein (complement factor H) are surprisingly and unexpectedly potent in regulating the complement activation path (the specification at page 4, 1st paragraph), the Examiner points out that SEQ ID NO: 9 is SCR 1-4

(module 1-4) of human complement factor H protein.

9. Claims 2, 17-20, 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by pir65 Accession No. S00524 (Dec. 31, 1993).

pir65 Accession No. S00524 teaches a molecule *comprising* complement control protein modules 1-4 of human complement factor H *having* the sequence of SEQ ID NO: 9 of the instant application. Note that the claimed recitation of intended use in inhibiting complement activation in instant claims 20 and 24 does not carry any patentable weight per se. A compound is the same compound irrespective of its intended use.

The reference teachings anticipate the claimed invention.

10. Claim 2 is objected to as being dependent upon a canceled base claim.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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